K101815

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

EnduRo Knee System
October 27, 2010

DEC 20 2010

COMPANY:	Aesculap Implant Systems, LLC 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Kathy A. Racosky 610-984-9291 (phone) 610-791-6882 (fax) Kathy.racosky@aesculap.com
TRADE NAME:	EnduRo Knee System
COMMON NAME:	Total Knee System
CLASSIFICATION NAME:	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
REGULATION NUMBER:	888.3510
PRODUCT CODE:	KRO

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the EnduRo Knee System is substantially equivalent to:

- NexGen Complete Knee Solution Rotating Hinge Knee, Zimmer, Inc. (K013385)
- Aesculap Implant Systems Columbus REVISION Knee System (K083772)

DEVICE DESCRIPTION

The EnduRo Knee System is a cemented prosthesis with a rotating hinge design. The femoral component, tibial plateau and extension stems are manufactured from CoCrMo. The tibial "gliding surfaces" and patella are manufactured from UHMWPE. The tibial mask is made from PEEK Optima® (LT1). The axial sleeve and femoral bushing components are produced from PEEK Optima® (LT1CA30). The system is made up of numerous components available in various sizes. The femoral, tibial plateau, and extension stems are also available with a ZrN (zirconium nitrate) coating. All components are sterile and for single use only.

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Aesculap Implant Systems EnduRo Knee System.

INDICATIONS FOR USE

The EnduRo Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

Hinge knee systems are designed for use in patients in primary or revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments are absent or insufficient. The femoral and tibial augments are to be attached to their respective components with a fixation screw or screws.

The EnduRo Knee System is intended for cemented use only.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems EnduRo Knee System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

The following tests were performed to support substantial equivalence:

- Range of Motion of the EnduRo Knee System
- Wear testing of the EnduRo Knee System
- Femoral Endurance Properties of the EnduRo Knee System
- Endurance Properties of the Modular Femoral Stem Assembly of the EnduRo Knee System
- Tibial Tray Endurance Properties of the EnduRo Knee System
- Endurance Properties of the rotating axis component in A/P direction of the EnduRo Knee System
- Endurance Properties of the Modular Tibial Stem Assembly of the EnduRo Knee System
- Varus-Valgus Endurance Properties of the EnduRo Knee System
- TibioFemoral Contact Area/Stress at Different Angles of Flexion for the EnduRo Knee System
- PatelloFemoral Lateral Subluxation Resistance of the EnduRo Knee System
- PatelloFemoral Contact Area/Stress at Different Angles of Flexion for the EnduRo Knee

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap Implant Systems LLC
% Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

DEC 20 2010

Re: K101815
Trade/Device Name: EnduRo Knee System
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: KRO
Dated: October 27, 2010
Received: October 28, 2010

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

DEC 2 0 2010

510(k) Number: K101815

Device Name: EnduRo Knee System

Indications for Use:

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Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101815